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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/002,878	11/14/2001	Albert Sattin	30429-CIP	6972

5179 7590 05/18/2004

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EXAMINER	
GUPTA, ANISH	

ART UNIT	PAPER NUMBER
1654	

DATE MAILED: 05/18/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/002,878	SATTIN ET AL.	
	Examiner	Art Unit	
	Anish Gupta	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 February 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-4 and 33-35* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4 and 33-35* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

1. The Amendment filed 2-9-04 is acknowledged. Claims 1 was amended, claims 5-32 were canceled and claims 33-35 were added. Claims 1-4 and 33-35 are pending in this application.

2. All rejection made in the previous office action and not cited herein, are hereby withdrawn.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 1, 3 remain 34 is rejected under 35 U.S.C. 102(b) as being anticipated by Sievertsson et al. (J. Med. Chem.)

The claims are drawn to a pharmaceutical preparation comprising a peptide having the formula pGlu-R1-Pro-NH2, wherein R1 is Leu, Tyr, or Val.

Applicants argue that there is no disclosure in the reference of saline as the carrier. There is no teaching or suggest that peptide pGlu-Trp-Pro-NH2 was administered in a pharmaceutical preparation that included saline. There mere fact that a control was employed neither teaches nor suggest that the that the control might be admixed and administered with an active ingredient, or that the control was constitute a "pharmaceutical carrier." Applicants have argued that the peptide in the reference was inactive and thus there would be no reason or suggestion to combine such a peptide with a pharmaceutical carrier to make a pharmaceutical preparation.

Applicants arguments have been considered but have not been found persuasive.

A "control," define in medicinal chemistry is a procedure undertaken in order to ensure that the experiment is conducted in a standard fashion and so that results are not unduly influenced by extraneous factors. For example, on the Drug Discovery and Development website, a control is defined as "A standard of comparison by which experimental results are evaluated. A control differs from the experiment in a single variable, and enables the assessment of significance of experimental results."[1] Here, the "control" is saline. Given that saline is the control, this would have to be the carrier employed since one would want to make sure that the in a peptide composition admixed with saline, that the peptide gave the desire result and not the saline. Note that a peptide composition admixed with saline and saline differ amongst one another in one variable, i.e. the peptide itself. Therefore, thus there is sufficient evidence that the reference discloses the use of saline as the desired carrier.

As for the arguments regarding the inactivity of the peptide, the standard for anticipation is the disclosure of the claimed subject matter within the reference. "A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." See MPEP 2131. Here, the reference as stated above and in the previous office action, disclose each and every element set forth in the claimed. Thus, the reference anticipates the claimed invention. The reference does not need to provide reason or suggestion to combine such a peptide with a pharmaceutical carrier to make a pharmaceutical preparation. The rejection was not obviousness under 103. Since the reference inherently discloses every element, the rejection is maintained.

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[1] http://www.dddmag.com/Glossary.aspx?RPTID=KWSRCH&SEARCHMETHOD=WORD&SEARCHWORD=Control

4. Claims 1 and 2 remain under 35 U.S.C. 102(b) as being anticipated by Kifaludy et al. for the reasons set forth in the previous office action and the reasons set forth below.

Applicants argue that US patent discloses a general formula which has seven different substitutents for X, three for Y and nine for W. Thus, this use of a generic formula to arrive at the specific composition, anticipation can only be found if the classes of substitutions are sufficient limited or well delineated. None of the examples specifically each the peptide pGlu-Leu-Pro-NH2.

Applicants arguments have been considered but have not been found persuasive.

When dealing with a genus species situation to establish a proper rejection under 102 of anticipation, one must be able to "at once envisage" the compound from the genus. See MPEP 2144.08. The MPEP states that when the compound is not specifically named, but instead it is necessary to select portions of teachings within a reference and combine them to arrive at a specific composition, anticipation can only be found if the classes of substituents are sufficiently limited or well delineated. Ex parte A, 17 USPQ2d 1716 (Bd. Pat. App. & Inter. 1990). If one of ordinary skill in the art is able to "at once envisage" the specific compound within the generic chemical formula, the compound is anticipated. MPEP 2131.02 Thus the genus has to be small enough to allow for one of ordinary skill in the art to envisage the claimed compound. Here, the reference disclose the compound D-Pyroglutamayl-L-leucyl-L-prolinamide (see col. 17, lines 40-42). The disclosure of this analog provides sufficient basis for the L-Pyroglutamyl-L-Leucyl-L-prolinamide to be "at once envisage[d]." Even taken to an extreme, say that this provide all D- and L- analogs, D-Pyroglutamayl-L-leucyl-L-prolinamide, there would only be eight different compounds (D-Pglu-L-Leu-L-Pro-NH2, L-Pglu-L-Leu-L-Pro-NH2, L-Pglu-D-Leu-L-Pro-NH2, L-Pglu-L-Leu-D-Pro-NH2, D-Pglu-D-eu-L-Pro-NH2, D-Pglu-D-Leu-D-Pro-NH2, L-Pglu-D-Leu-D-Pro-NH2, D-Pglu-

L-Leu-D-Pro-NH2). The MPEP states that a genus comprised of 20 compounds is sufficient to allow one to envisage each member. See MPEP 2144.08. Here the genus is well within the 20 that permits one to "at once envisage" each member.

Rejection is maintained.

5. Claims 1,2, 4 remain rejected under 35 U.S.C. 102(b) as being anticipated by Szirtes et al. (J. Med. Chem.).

The claims are drawn to a pharmaceutical preparation comprising a peptide having the formula pGlu-R1-Pro-NH2, wherein R1 is Leu, Tyr, or Val.

Applicants argue that the reference only discloses compounds that were administered 5 ot 80 mg/kg intravenously. There is no disclosure of any formulation.

Applicants arguments have been considered but have not been found persuasive.

As applicants acknowledge, the reference discloses the administration of the peptide to rates at a concentration range of 5 to 80 mg/kg 10 μg intravenously (see page 744). An intravenous formulation has to be a liquid formulation. To achieve such a liquid formulation, one has to use a carrier. Even if the water is used to achieve the liquid formulation, the reference still teaches the claimed invention since water would be the carrier. Thus, it is inherent in the administration to rats at 5 to 80mg/kg, that the peptide and a pharmaceutical carrier are present, especially for intravenous administration.

The rejection is maintained.

New Grounds for Rejections

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

6. Claims 33 and 35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sivertsson et al. in view of Tamura et al. (US 4610821) or Plotnikoff et al. (US 3865934).

The reference of Sivertsson et al. teach intravenous administration of TRH like analogs (pGlu-Val-Pro-NH2 and pGlu-Leu-NH2) had powerful anticataleptic effect when compared to native TRH peptide (see page 744). The reference disclose i.v. administration of the peptide at a dosage of 5 to 80mg/kg. The difference between the prior art does not disclose the use of isotonic formulation.

However, the reference of Tamura et al. teach that TRH and TRH like peptides can be formulated using saline solution (see col. 7, lines 45-55 and col. 55, lines 24-30). Similarly, the reference of Plotnikoff et al. teach TRH peptide, for parenteral administration, can be prepared by

dissolving the TRH peptide in water, and if desired, the solution is made isotonic and/or buffered to a pH between 7 and 7.8 (see col. 2, lines 63-65). Therefore, since Sivertsson et al. teach the administration of TRH-like and TRH via intravenous administration, it would have been obvious to formulate the anticataleptic peptides in isotonic solution. This is because native TRH is prepared for parenteral administration in a isotonic solution. One would be motivated to formulate the TRH-like peptide in the same manner as TRH.

7. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anish Gupta whose telephone number is (571)272-0965. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback , can normally be reached on (571) 272-0961. The fax phone number of this group is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

5/10/04

Anish Gupta
Patent Examiner

BRENDA BRUMBACK
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600